REMARKS

Applicants respectfully request reconsideration of the subject matter identified in caption, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow.

Claims 19, 20 and 23-37 are pending in the application.

Turning now to the Official Action, claims 19, 20 and 23-37 stand rejected under 35 U.S.C. § 112, first paragraph. For at least the reasons that follow, withdrawal of the rejection is in order.

The Official Action asserts that the specification, while being enabling for auranofin, SKF-105809 and lactoferin as the interleukin 1 antagonist and enabling for lisophyline, A802715 and sulphasalazine as the TNF alpha antagonist, does not reasonably provide enablement for any interleukin 1 antagonist or any TNF alpha antagonist. The Official Action further asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. (See Official Action at page 2). Applicants respectfully disagree.

In particular, Applicants believe that the specification does disclose enough to enable one of ordinary skill in the art to practice the invention without undue experimentation. Specifically, it has been decided that some experimentation is often expected in unpredictable areas or technologies. *See, In re Angstadt*, 537 F.2d at 503, 190 USPQ at 218. Furthermore, it is understood that the test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in

which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *See, Johns Hopkins University v. Cellpro Inc.*, 152 F.3d 1342, 47 USPQ2d 1703 (Fed. Cir. 1998). In this regard, Applicants submit that because IL-1 and TNF-alpha antagonists are well-known compounds, any experimentation needed to practice the claimed invention would be routine, not undue. This position is supported by the attached technical references and the Declaration of Dr. Jean-Claude Yadan, which prove that those of ordinary skill in the art are familiar with IL-1 and/or TNF-alpha antagonist compounds, and that the specification, which discloses antagonist compounds with varying chemical structures, would be understood to convey that Applicants' invention can include any compound that exhibits IL-1 and/or TNF-alpha antagonistic activity, regardless of the compound's chemical structure. Specifically, Dr. Yadan states that one of ordinary skill in the art having read the instant specification and being aware of the available technical literature, would be able to practice the invention without undue experimentation. (See Declaration for example, at paragraphs (5) and (8).)

Applicants also note that the Official Action asserts that "while the instant specification does provide working examples, the examples are limited to the specific antagonists recited on page 9 of the specification." (See Official Action at page 4.) However, it has been decided that it may not be necessary to have any working embodiments at all in order to satisfy the requirements of § 112, first paragraph, even in the chemical arts. *See, In re Strahilevitz*, 668 F.2d 1129, 212 USPQ 561 (CCPA 1982). That is, where an invention resides in the use of known prior art techniques, a disclosure without any working embodiments can be sufficient to

enable even broad claims to an invention. In this regard, the attached technical references and the Declaration of Dr. Yadan make it clear that the claimed compositions are obtained through the use of known IL-1 and TNF-alpha antagonist compounds. For example, the attached technical references show that IL-1 and TNF-alpha antagonist compounds similar to the compounds disclosed in the instant specification are well-known and readily-identifiable. Moreover, from the comments of Dr. Yadan, it is clear that those of ordinary skill in the art, having read the instant specification, would recognize that Applicants' disclosure of antagonist compounds of varying chemical structure was provided to convey that Applicants' invention can include any compound, regardless of its chemical structure, which exhibits IL-1 and/or TNF-alpha antagonist activity. Because such compounds are well-known and readily-identifiable, Applicants submit that it is unnecessary to provide examples, which disclose every single well-known and readily-identifiable IL-1 and TNF-alpha antagonist compound to satisfy the requirements of § 112, first paragraph. With respect to Applicants' reliance on the attached technical references, Applicants note that *In re Strahilevitz* established that the reliance on U.S. patents and scientific literature to show that prior art information is known, has been permitted.

Applicants also wish to point out that, as explained in the Declaration of Dr. Yadan, the present application describes the compounds to be used in the defined compositions in a functional manner because it is the compounds' functional characteristics, and not their chemical structures, which make the compounds suitable for use in the claimed compositions. Dr. Yadan explains that this is evident from Applicants' disclosure of antagonist compounds having varying chemical structures. Accordingly, Applicants submit that in a case like the present application,

where a compound's functional characteristics, not its chemical structure, are the features that make the compound suitable for use in the claimed compositions, it should not be necessary for Applicants to disclose every single chemical structure of such compounds to satisfy the requirements of § 112, first paragraph.

Along these lines, Applicants submit that under European Patent Law, claims including a functional definition are acceptable. Specifically, the guidelines for examination in the European Patent Office (Part C-III, 4.7) state:

> ... claims which attempt to define the invention, by a result to be achieved ... may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely **without unduly restricting the scope of the claims** and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation (see T68/85, OJ6/1987, 22A). (Emphasis added.)

Applicants submit that the terms "IL-1 antagonist" and "TNF-alpha antagonist" are the most appropriate terms to define the compounds employed in the defined compositions, and that these compounds cannot be more precisely defined without unduly restricting the scope of the pending claims. As explained above, and in the attached Declaration of Dr. Yadan, these terms are well-known in the art and are widely-used by those possessing ordinary skill. Clearly, the well-known and readily-identifiable nature of these antagonist compounds is evident from the attached technical references as well as the numerous prior art references cited by the Examiner. Moreover, the specification discloses tests, which are suitable to identify compounds as IL-1 and/or TNF-alpha antagonists. (See specification, for example, at page 7, ¶¶ 28-30). Accordingly, Applicants submit that those of ordinary skill in the art would be readily able to identify compounds as IL-1 and/or TNF-alpha

antagonists and, therefore, would be able to make and/or use the claimed invention without undue experimentation.

Additionally, Applicants wish to point out that in the recent § 112, first paragraph, decisions *University of Rochester v. G.D. Searle & Co., Inc.*, 249 F. Supp. 216 (W.D.N.Y. 2003) and *University of Rochester v. G.D. Searle & Co. Inc.*, U.S. Ct. of Appeals for the Fed. Cir. Docket No. 03-1304, decided February 13, 2004, invalidity under § 112, first paragraph, was found where functionally described compounds were not only not disclosed in the specification but were not shown to be known at all. (Emphasis added.) Specifically, the Court of Appeals stated

> ... it is undisputed that the '850 patent does not disclose any compounds that can be used in the claimed methods. The claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known. (See page 17 of the CAFC decision.) (Emphasis added.)

The Court of Appeals distinguished this situation from *In re Herschler*, 591 F.2d 693 (CCPA 1979), wherein the requirements of § 112, first paragraph, were deemed to be met by the disclosure of a single example of a "physiologically active steroidal agent." In particular, the Court of Appeals stated that there was no question that unlike the functionally described compounds in the University of Rochester patent, numerous physiologically active steroidal agents were known to those of ordinary skill in the art. (See pages 19-20 of the CAFC decision.) (Emphasis added.)

Clearly, the situation in the present application is analogous to the situation in *In re Herschler*. Specifically, unlike the compounds in the University of Rochester patent, IL-1 and TNF-alpha antagonists are compounds that are "known to those of ordinary skill in the art."

Finally, Applicants recognize that the Official Action relies on *In re Dreshfield,* 110 F.2d 235, 45 USPQ 36 (CCPA 1940), to support the position that cases involving chemicals and chemical compounds, which "differ radically in their properties" must appear in an applicant's specification. Applicants submit, however, that the Official Action's reliance on *In re Dreshfield* in support of the § 112, first paragraph, rejection of the pending claims in this application appears to be improper.

In re Dreshfield involved a case where an Applicant's original disclosure was limited to specific antioxidant compounds and wherein the claims in the application defined compounds that were broader than those disclosed in the specification. (Emphasis added.) (See *In re Dreshfeld,* for example, at page 41.)

Specifically, at page 41 of the *Dreshfeld* decision, it is explained that in the application at issue:

> ...claims include compounds not disclosed in appellant's application here involved as originally filed; that all of the antioxidants disclosed in appellant's specification (fourteen in number) are "di-aryl amino compounds;" that claim 15 is broader than appellant's disclosure in that it calls for "an antioxidant aromatic amino compound having *at least two* [which, of course, would include more than two] of its amino hydrogen atoms replaced by aryl groups," whereas, appellant disclosed in his involved application as originally filed compounds having *but two* of the amino hydrogen atoms replaced by aryl groups (italics ours); that claim 16 is broader than appellant's disclosure in that it calls broadly for an antioxidant *aromatic amino compound*, whereas, appellant disclosed in his application as originally filed only *di-aryl* amino compounds ...

In contrast, the compounds identified on page 9 of the current specification are merely examples of suitable antagonist compounds. Throughout the specification, Applicants regularly refer to IL-1 and TNF-alpha antagonist compounds generally. Moreover, Applicants submit that because the specification discloses exemplary compounds having different chemical structures, it should be understood

that the specification provides broad disclosure for compositions, which can include any compound that exhibits IL-1 and/or TNF-alpha antagonistic activity. Moreover, the compounds disclosed in the application of *In re Dreshfeld* were catalytic in nature. Therefore, the effectiveness of the compounds could only be determined by experiments and any generalizations regarding their effectiveness was deemed to be meaningless since the effectiveness of one type of compound could not be relied upon to indicate that other compounds of the same type would also be effective. (See *In re Dreshfeld* at page 38.) In contrast to the catalytic compounds of *In re Dreshfeld,* however, it is believed that the antagonist compounds of the present invention can be referred to generally because it is believed that any compound exhibiting IL-1 and/or TNF-alpha antagonist activity would be effective in the claimed invention. Thus, unlike the compounds of *In re Dreshfeld,* Applicants do not believe that it would be necessary to conduct an experiment to determine the effectiveness of each compound of the IL-1 and/or TNF-alpha antagonist type. Accordingly, it appears that that *In re Dreshfield* cannot be properly applied in rejecting the claims of the present application because, unlike the compounds claimed in *In re Dreshfeld;* the compounds claimed in the instant application are (1) not broader than those generally described in Applicants' disclosure, and (2) do not "differ radically in their properties."

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph, rejection.

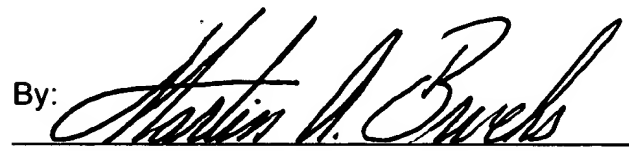
From the foregoing, Applicants earnestly solicit further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: May 25, 2004

By: 

Martin A. Bruehs
Registration No. 45,635

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Attachments: Declaration of Dr. Yadan
Dr. Jean-Claude Yadan's Curriculum Vitae,
Research Experience and List of Publications (Appendix I)
List of Technical References (Appendix II)